STATE OF MISSOURI MISSOURI BOARD OF PHARMACY

IN RE:

PHARMACARE PLUS PHARMACY 6720 Sands Point Dr. Ste 105 Houston, TX 77074 License No. 2016008986

Complaint No. 2017-002870

SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND PHARMACARE PLUS

COMES NOW PHARMACARE PLUS PHARMACY ("Respondent" or the "Pharmacy" or "Pharmacare Plus") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate as a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri ("AHC") and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witness appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its

permit. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For purposes of settling this dispute only, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true, and that Respondent's license as a pharmacy, numbered 2016008986, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS

- 1. The Missouri Board of Pharmacy is an agency of the State of Missouri created and established pursuant to §338.110, RSMo (2016), 1 for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.
- 2. Pharmacare Plus, 6720 Sands Point Dr. Ste 105, Houston, TX 77074 is permitted by the Board under license number 2016008986. Respondent's license was at all times relevant herein current and active.
- 3. On May 9, 2017, the Board received a Uniform Complaint Report from a pharmacist working at Southside Family Practice, 1031 Bellevue, Suite 300, St. Louis, MO 63117. The report stated that the pharmacist was alerted that a patient received numerous prescriptions for lidocaine 5% ointment and diclofenac 3% gel from two different out of state pharmacies, one of which was Pharmacare Plus.

¹ All statutory references are the to the Revised Statutes of Missouri (2016) unless otherwise noted.

4. The patient told the Board's investigator that she did not know how Pharmacare Plus obtained her information and that she did not pay anything for the prescriptions, so they must have been billed to her Medicare Part D insurance. The reporting pharmacist believed that the patient's Medicaid was also paying part of the cost.

Records Requests

- 5. On May 15, 2017, the Board's investigator contacted Pharmacare Plus and asked to speak to the Pharmacist-in-Charge ("PIC"). The investigator was told that the PIC was not available and would return the call. The customer care representative provided a fax number for Pharmacare Plus, and the Board's investigator faxed a Pharmacy Drug Utilization Records Request to Pharmacare Plus.
- 6. On May 19, 2017, the Board's investigator had not received a call from the PIC and had not received any response to the document request even though the regulations require that pharmacies respond within three days. The Board's investigator called Pharmacare Plus and was again told that the PIC was not available.
- 7. The Board's investigator faxed a duplicate copy of the document request to a different fax number provided by the customer care representative.
- 8. On May 22, 2017, the Board's investigator had still not received a response to either document request. The investigator called again and was again told that the PIC was not available. The investigator spoke to the pharmacy manager, who asked that the document request be emailed.
- 9. On May 31, 2017, no documents had been received. The Board's investigator sent a certified mail request for the records.

- 10. The requested documents were finally provided on June 7, 2017.
- 11. On August 10, 2017, the Board's investigator requested, via certified mail, a copy of 72 hard copy prescriptions that were filled for prescriptions other than diabetic testing supplies.
- 12. On August 17, 2017, an employee in the credentialing department at Pharmacare Plus, contacted the Board to express concerns regarding HIPPA. The same day, the Board's investigator provided a HIPPA statement.
 - 13. As of September 15, 2017, no records had been received.
- 14. On September 18, 2017, the investigator requested the records again via certified mail.
- 15. On September 19, 2017, Pharmacare Plus finally faxed the requested records, but they were not legible. The Board's investigator requested that they be mailed. The legible copies were received on October 3, 2017.
- 16. The hard copy records indicated that fax headers were whited out before they were faxed to the Board.

Efforts to Speak to a Pharmacist

- 17. On September 27, 2017, the Board's investigator attempted to speak with a pharmacist. At approximately 3pm, the investigator was told that a temporary pharmacist had been working that day but had just left and the pharmacy was shut down.
- 18. On October 2, 2017, the Board's investigator tried again to speak to the PIC. As of October 13, 2017, no return call was received despite multiple messages and an email.

- 19. On October 16, 2017, the Board's investigator contacted the Texas Board of Pharmacy and asked a compliance officer to contact the PIC. On that date, the PIC finally returned the Board investigator's calls.
- 20. The PIC stated that she was not aware of the pharmacy closing early on September 27, 2017, the date that the Board's investigator was told that the pharmacy had closed before 3pm.
- 21. On October 17, 2017, the Board's investigator called Pharmacare Plus and pressed the button in the automated system to speak to a member of the pharmacy staff. Two efforts to speak to pharmacy staff were transferred to voicemail without any staff answering.
- 22. Later in the day on October 17, 2017, the Board's investigator called again and reached a customer representative. The investigator asked to speak to a pharmacist. The investigator was repeatedly told there were phone congestion issues. The investigator was placed on hold for 27 minutes, then was provided an email address to submit a question.
- 23. The Board's investigator then contacted the PIC and asked if there were problems with the phone lines. The PIC said she was not aware of any problems.
- 24. On October 26, 2017, the PIC sent a message to the Board's investigator stating, "I just want to let you that I resigned from pharma care plus pharmacy because they are not giving you or myself the answers you are asking."

JOINT CONCLUSIONS OF LAW

25. Respondent's actions violated 20 CSR § 2220-2.080(12), which provides:

The EDP system shall be able to provide a listing of drug utilization for any drug for a minimum of the preceding twenty-four- (24-) month period. Drug utilization information shall be available by date(s), specific drug product, patient name, or practitioner. If requested to do so, the pharmacy shall have three (3) working days to provide the report.

26. Respondent's actions violated 20 CSR § 2220-2.080(4), which provides that "Prescription hard copies must be retrievable at the time of inspection" and under 20 CSR § 2220-2.080(7), which requires that:

Any EDP system must be capable of producing the record required by this rule and said records shall be readily retrievable online. Readily retrievable is defined as providing EDP records immediately or within two (2) hours of a request by an inspector or by making a computer terminal available to the inspector for immediate use.

- When asked to provide records initially, it took more than twenty days for the Board to obtain records required to be provided within three days.
- 28. When asked to provide records that must be available within two hours, it took forty days for the Board to obtain these records.
- 29. Cause also exists to take disciplinary action against Respondent's pharmacy permit under 20 CSR § 2220-2.190, which requires that a pharmacist offer to counsel patients when dispensing prescription medication. For mail-order prescriptions, "a written offer to counsel with a telephone number of the dispensing pharmacy at no cost to the patient must be supplied."
- 30. On at least two occasions, the Board's investigator was not able to reach a pharmacist when requested.
- 31. As a result, Respondent's permit is subject to discipline under 20 CSR § 2220-2.010(1)(0), which provides:
 - (O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

- 32. Cause exists to take disciplinary action against Respondent's pharmacy permit under § 338.055.2(5), and (6)), RSMo, which provides:
 - 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

- (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;
- (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

33. Violation of the regulations regarding providing documents in a timely manner when requested and violation of the requirement that a pharmacist be available to counsel patients are violations of rules and regulations adopted pursuant to Chapter 338, RSMo.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

- 1. Respondent's pharmacy license numbered 2016008986 shall be placed on PROBATION for a period of THREE YEARS ("disciplinary period"). The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:
 - A. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.
 - B. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.
 - C. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by Respondent, and the individuals' current home addresses and telephone numbers.
 - D. If, after disciplinary sanctions have been imposed, the Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.
 - E. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.
 - F. Respondent shall not serve as an intern training facility for interns.
 - G. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be provided a minimum of three (3) business days' notice for in-person meetings held in Missouri.
 - H. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.
 - I. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

- 2. Upon the expiration of said discipline, Respondent's license as a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.
- 3. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.
- 4. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.
- 5. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except

by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

6. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs, and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. §1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,
REQUESTS
DOES NOT REQUEST
THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS
SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S
PERMIT TO OPERATE AS A PHARMACY.

Respondent understands that it may, either at the time the Settlement Agreement is signed by all parties, or within fifteen (15) days thereafter, submit the Settlement Agreement to the Administrative Hearing Commission for determination that the facts agreed to by the parties

constitute grounds for disciplining Respondent's permit. If Respondent desires the Administrative Hearing Commission to review this Agreement, it may submit its request to: Administrative Hearing Commission, located at United States Post Office Building, Third Floor, 131 West High Street, Jefferson City, MO 65101 (Mailing address: PO Box 1557, Jefferson City, MO 65102).

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director.

RESPONDENT **PETITIONER** MISSOURL BOARD OF PHARMACY PHARMACARE PLUS PHARMACY , As Auth Agent for PHARMACARE PLUS Kimberly Grinston Executive Director PHARMACY Date: TGH LITIGATION LLC By: Joanna Trachtenberg, #63298 28 N. 8th St., Suite 317 Columbia, MO 65201 Phone: 573-256-2850 Fax: 573-213-2201 joanna@tghlitigation.com Attorneys for Misso wi Board of Pharmacy Date: March 18, 2020